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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/642,272	08/18/2003	Fumiyuki Hattori	58777.000012	3248

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EXAMINER	
NOBLE, MARCIA STEPHENS	
ART UNIT	**PAPER NUMBER**
1632	

DATE MAILED: 01/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/642,272	HATTORI ET AL.	
	Examiner	Art Unit	
	Marcia S. Noble	1632	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-32 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-32 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-32 are pending.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-14, drawn to method of and agent for treating a disease associated with decreased expression of AOP-1 gene or AOP-1, classified in class 514, subclass 44 or 2.

II. Claims 15-16, drawn to diagnostic method for a disease associated with decreased expression of AOP-1 gene, classified in class 435, subclass 4.

III. Claims 15-16, drawn to diagnostic method for a disease associated with decreased expression of AOP-1, classified in class 435, subclass 4.

IV. Claims 17-18, drawn to diagnostic kit for a disease associated with decreased expression of AOP-1 gene, classified in class 435, subclass 4.

V. Claims 17-18, drawn to diagnostic kit for a disease associated with decreased expression of AOP-1, classified in class 435, subclass 4.

VI. Claims 19 and 20, drawn to non-human transgenic animal suitable for the use as a pathologic model of a disease associated with decreased expression of AOP-1 gene or AOP-1, classified in class 800, subclass 13.

VII. Claims 21-22, drawn to a transformed tissue or cell suitable as a model of a disease associated with decreased expression of AOP-1 gene or AOP-1, classified in class 435, subclass 4.

VIII. Claim 23, drawn to a method for screening a material enhancing the expression, production, or function of AOP-1 using an transgenic animal tissue or cell model, classified in class 800, subclass 3.

IX. Claims 24-28, drawn to method of screening a material enhancing AOP-1 expression comprising contacting an in vitro expression system, a report gene expression system, a AOP-1 or target molecule to determine transcript expression levels, protein or target molecule levels, classified in class 435, subclass 375.

X. Claims 29-32, drawn to method of screening a material enhancing AOP-1 comprising contacting with AOP-1 or target molecule of AOP-1 to determine the antioxidant or peroxynitrite scavenging activity of AOP-1, classified in class 435, subclass 375.

2. Restrictions

The inventions are distinct, each from the other because of the following reasons:

A. Inventions I-V, VIII, IX and X are unrelated methods. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions methods of treatment require different subjects and step then methods of diagnosis which require different steps and reagents than methods of screening for an agent. The method of treatment requires administering a gene, protein or small molecule to a subject with the outcome

of alleviating a disease associated with decreased AOP-1, whereas a method of disagnosis uses a sample from a subject in a methodology that detects the levels of AOP-1. In contract to both treatment and diagnosis methods, a screening method may not utilize a subject at all and may be done completely in vitro.

B. Inventions II-V and I, VI, VIII, IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions can be carried out independently. While the transgenic animal can be used to screening of agents, agents can be screening by in vitro method that do not employ a animal model. Similarly the transgenic animal of invention II would not be used in methods of treatment or methods of diagnosis.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

3. Species Elections

A. Claims 7 are generic to a plurality of disclosed patentably distinct species comprising chronic heart failure, ischemic heart failure, ischemic heart disease, rheumatoid arthritis, neurodegenerative disease, hepatic disease or renal failure.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

B. Claims 24-28 are generic to a plurality of disclosed patentably distinct species comprising transformed cell, an in vitro expression system having a transcriptional regulatory region of AOP-1 gene and AOP-1 gene, a reporter gene to detect the expression level of AOP-1 gene, reporter gene, AOP-1, or a target molecule of AOP-1. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

C. Claims group I, group II-V, and group VII are generic to a plurality of disclosed patentably distinct species comprising chronic heart failure, ischemic heart failure, rheumatoid arthritis, neurodegenerative diseases, hepatic disease, or renal failure. If any one of groups I-V, VII is elected, applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

D. Claim 23 is generic to a plurality of disclosed patentably distinct species comprising transgenic animal, transformed tissue, or transformed cell. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement may be traversed (37CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CRF 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marcia S. Noble whose telephone number is (571) 272-5545. The examiner can normally be reached on M-F 9 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marcia S. Noble

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